

## Message Text

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62

ORIGIN HEW-06

INFO OCT-01 EUR-12 EA-10 ISO-00 OES-05 /034 R

66617

DRAFTED BY: DHEW/FDA/JRWEINROTH, MD

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

EUR/WE:WHMARSH (INFO)

EUR/IB:MDURKEE (INFO)

EA/PRCM:RHOLMES (INFO)

----- 030564

R 282221Z MAR 75

FM SECSTATE WASHDC

TO AMEMBASSY PARIS

AMEMBASSY MADRID

AMCONSUL HONG KONG

UNCLAS STATE 071108

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, FR, HK, SP

SUBJECT: FDAADVISORY - CONTAMINATED ANTI - RH TYPING SERUM,  
(ANTI - E)

1. FDA ADVISES THAT THE PRODUCT ANTI - RH TYPING SERUM,  
ANTI - RH (ANTI - E), SLIDE AND RAPID TUBE TEST, MANUFACTURED  
BY SCHERING DIAGNOSTICS, SCHERING COPRORATION, PORT READING,  
MJ 07064 IN 2 ML AND 5 ML VIALS AND 1,000 ML BULK, LOT NUMBERS  
AS FOLLOWS: 720-1 (5 ML. VIALS), 721 (2 AND 5 ML. VIALS), 722  
(1000 ML. BULK) ARE CONTAMINATED WITH A RARE GOA ANTI-BODY  
WHICH COULD LEAD TO FALSE TEST RESULTS.

2. FOREIGN CONSIGNEES AS FOLLOWS: LOT 720-1 (EXPIRATION DATE  
6/12/75)- FOUR SHIPMENTS TO SPAIN WERE MADE TO DINTER, S.A.  
ENCARNACION 123, BARCELONA, 12, SPAIN. SHIPMENTS TO THIS  
CONSIGNEE INCLUDE INVOICE NUMBER 88173 20/5 ML. VIALS ON  
6/21/74, INVOICE NO. 88327, 50/5 ML. VIALS ON 6/28/74,  
INVOICE NO. 89559, 30/5 ML. VIALS ON 11/6/74, INVOICE NO.  
89559, 20/5 ML. VIALS ON 12/11/74.

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3. LOT 721 (EXPIRATION DATE 1/23/76 FOR 5 ML. VIALS, AND 11/8/75 FOR 2 ML. VIALS).

SHIPMENTS OF 40/5 ML. VIALS, INVOICE NO. 90102 WERE MADE TO DINTER, S.A. ENCARNACION 123, BARCELONA, 12, SPAIN.

2 ML. VIALS WERE SHIPPED TO HONG KONG PHARMACEUTICAL DISTRIBUTORS 45 HANKOW ROAD, SECOND FLOOR "H" TSIM SHA TSUI, KOWLOON, HONG KONG. SHIPMENTS TO THIS DISTRIBUTOR INCLUDE INVOICE NO. 90076 4/2 ML. VIALS ON 1/29/75, INVOICE NO. 89668, 2/2 ML. VIALS ON 11/21/74.

4. LOT 722 (EXPIRATION DATE 10/24/74). THIS ENTIRE LOT WAS SHIPPED IN 5/1000 ML. BULK CONTAINERS TO PRODUTEXA CO., 61 BOARDWAY, NEW YORK, NY. 1006 AND WAS SUBSEQUENTLY EXPORTED TO CENTRAL NATIONAL DE TRANSFUSION SANGUINE 6 RUE ALEXANDRE - CABANEL, PARIS XV, FRANCE.

5. POSTS ARE REQUESTED TO DETERMINE IF FOREIGN CONSIGNEES HAVE BEEN INFORMED BY SCHERING CORPORATION OF THE NATURE OF THE PROBLEM. KISSINGER

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## Message Attributes

**Automatic Decaptoning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** FOOD & DRUG REGULATIONS, IMMUNIZATION  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 28 MAR 1975  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
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**Document Unique ID:** 00  
**Drafter:** DHEW/FDA/JRWEINROTH, MD  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
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**Office:** ORIGIN HEW  
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**Original Handling Restrictions:** n/a  
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**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
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**Review Authority:** ShawDG  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 20 JUN 2003  
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**Review Transfer Date:**  
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**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDAADVISORY - CONTAMINATED ANTI - RH TYPING SERUM, (ANTI - E)  
**TAGS:** OGEN, ETRD, TBIO, FR, HK, SP  
**To:** PARIS HONG KONG  
**Type:** TE  
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